4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-D-3462]

Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a revised draft guidance entitled "Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs." This revised draft guidance addresses the verification systems that manufacturers, repackagers, wholesale distributors, and dispensers must have in place to comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Drug Supply Chain Security Act (DSCSA). Specifically, this revised draft guidance covers the statutory verification system requirements that include the quarantine and investigation of a product determined to be suspect and the quarantine and disposition of a product determined to be illegitimate. The revised draft guidance also addresses the statutory requirement for notification to the Agency of a product that has been cleared by a manufacturer, repackager, wholesale distributor, or dispenser (also referred to as "trading partners") after a suspect product investigation because it is determined that the product is not an illegitimate product. Finally, the revised draft guidance addresses the statutory requirement for responding to requests for verification and processing saleable returns.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-D-3462 for "Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs; Draft Guidance for Industry; Availability." Received comments will be placed in the

docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CDER at at 1-800-835-4709 or 240-402-8010. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Sarah Venti, Office of Compliance, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-3130, drugtrackandtrace@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a revised draft guidance for industry entitled "Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs." The DSCSA (Title II of Pub. L. 113-54) was signed into law on November 27, 2013. Section 202 of the DSCSA added section 582 to the FD&C Act (21 U.S.C. 360eee-1), which established the requirement that trading partners have systems in place to enable them to comply with certain verification obligations. This revised draft guidance provides recommendations for robust verification systems for the determination, quarantine, and investigation of suspect products, as well as the quarantine, notification, and disposition of illegitimate products. This revised draft guidance also addresses: the manner in which FDA recommends that trading partners submit cleared product notifications (i.e., notifications that a suspect product is not an illegitimate product); the statutory requirements for responding to requests for verification; and the statutory requirements for processing saleable returns.

In the *Federal Register* of October 25, 2018 (83 FR 53880), FDA announced the availability of a draft guidance entitled "Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs" dated October 24, 2018. FDA received several

comments on the draft guidance, which have been taken into consideration. In response to comments received from stakeholders, this draft guidance revises the October 2018 draft guidance to: (1) provide FDA's interpretation of what "possession or control" means as used throughout the DSCSA; (2) explain that the guidance uses the term *verification* in referring to both the broad set of requirements set forth in paragraphs (b)(4), (c)(4), (d)(4), and (e)(4) of section 582 of the FD&C Act in addition to using the term with the meaning defined in section 581(28) of the FD&C Act, where appropriate to the context; (3) recognize that, in cases where the DSCSA directs trading partners to coordinate with one another during investigations and dispositions of products, certain types of trading partners are typically better suited to handle specific aspects of those statutory requirements; (4) clarify that FDA will make requests for verification if a trading partner is in possession or control of a product that the Agency has determined to be suspect product; (5) clarify FDA's understanding of what "electronic quarantine" means; (6) clarify when samples of illegitimate product should be retained; (7) clarify FDA's expectations related to the requirements for responding to requests for verification from authorized trading partners; (8) inform trading partners of the information that should be communicated among trading partners when determining whether a suspect product is illegitimate; and (9) inform trading partners of the information that should be included when responding to requests for verification from FDA and other trading partners (where applicable), and verifying saleable returned product. In addition, editorial changes were made to improve clarity.

This revised draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on "Verification Systems Under the Drug Supply Chain Security Act for Certain Prescription Drugs." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance includes information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501-3520) (PRA). FDA intends to solicit public comment and obtain OMB approval for any information collections recommended in this guidance that are new or that would represent substantive or material modifications to those previously approved collections of information found in FDA regulations or guidance. III. Electronic Access

Persons with access to the internet may obtain the guidance at either https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs or https://www.regulations.gov.

Dated: March 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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